

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

15 Mar 2022

### Double-blind placebo-controlled clinical trial of evaluating the effectiveness of Ivermectin in treatment of patients admitted with COVID-19 in 2021

#### Protocol summary

##### Study aim

Determining the effect of ivermectin on RT-PCR test, clinical improvement, mortality and duration of hospitalization in patients admitted with COVID-19

##### Design

Clinical trial with control group, parallel groups, double-blind, randomized, phase 3 on 1000 patients. Patients will be divided into two groups by a simple randomization method with a table of random numbers. The control group will receive standard and placebo treatment and the intervention group will receive Ivermectin for three days in addition to the standard treatment.

##### Settings and conduct

COVID-19 positive rapid test or RT-PCR patients admitted to Buali and Imam hospitals of Sari, Razi hospital of Qaemshahr, Imam Hossein hospital of Neka and Imam hospital of Fereidoonkenar will be divided into two groups of intervention and control. The present study will be double-blind so that patients and physicians will be unaware of how the intervention and control groups assigned.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with COVID-19 positive rapid test or RT-PCR; aged >5 years; weight more than 15 kg and without liver and lung disease and acquired immunodeficiency and pregnancy lactation and without treatment with antiviral drugs before and during the study are included.

##### Intervention groups

Intervention group: Iranian standard treatment protocol for COVID-19 in addition to 6mg Ivermectin tablet made by Alborz Daru Company of Iran for 3 days. Control group: In the control group, placebo tablets made by Alborz Daru Company of Iran with the same shape, color and weight based dose of ivermectin will be used for three days.

##### Main outcome variables

Clinical improvement, Duration of hospital stay, Rate of Mortality

#### General information

##### Reason for update

Increase in sample size and pharmaceutical company

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20111224008507N5**

Registration date: **2021-02-22, 1399/12/04**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-03-04, 1399/12/14**

Update count: **1**

##### Registration date

2021-02-22, 1399/12/04

##### Registrant information

###### Name

Mohammadsadegh Rezai

###### Name of organization / entity

Mazandaran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 15 1325 7230

###### Email address

rezai@mazums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-02-19, 1399/12/01

##### Expected recruitment end date

2021-08-22, 1400/05/31

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Double-blind placebo-controlled clinical trial of evaluating the effectiveness of Ivermectin in treatment of patients admitted with COVID-19 in 2021

**Public title**  
Evaluation of the effect of Ivermectin in treatment of patients admitted with COVID-19

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
 Patients with positive coronavirus rapid test or RT-PCR  
 Age>5 years Weight >15 kg No treatment with antiviral drugs before and during the study Informed consent for participation  
**Exclusion criteria:**  
 Underlying liver and kidney disease Patients with acquired immunodeficiency Pregnancy and lactation

**Age**  
From 5 years old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Investigator

**Sample size**  
Target sample size: 1000

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
First, using the Random number generation plugin in excel software, a table of random numbers from 1 to 1000 is prepared in a non-sequential and scattered manner, and the numbers are assigned to two intervention and control groups of 500 cases. The randomization process is performed by the methodology consultant and clinical researchers are not aware of the randomization process and will only be provided with random codes from 1 to 1000.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
After selecting the samples, none of the participants will be aware of randomization and allocation to groups. Physicians will be given a table of pre-coded numbered numbers and patients will be entered into the study in order of table numbers. Therefore, the present study will be double-blind. Ivermectin and placebo tablets will be in the same shape, color and size and will be delivered to the patient/parents in a package.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

##### Street address

Vice chancellor for Research, Moallem square, Sari

##### City

Sari

##### Province

Mazandaran

##### Postal code

4712855689

#### Approval date

2021-01-27, 1399/11/08

#### Ethics committee reference number

IR.MAZUMS.REC.1399.915

## Health conditions studied

### 1

#### Description of health condition studied

COVID-19 infection

#### ICD-10 code

U07.1

#### ICD-10 code description

COVID-19, virus identified

## Primary outcomes

### 1

#### Description

Reduction in persistent cough

#### Timepoint

Daily until improvement

#### Method of measurement

Question from the patient

### 2

#### Description

Negative RT-PCR result

#### Timepoint

6 days after the intervention

#### Method of measurement

RT-PCR

### 3

#### **Description**

The main complaints recovery time

#### **Timepoint**

Daily until symptoms resolve

#### **Method of measurement**

Checklist containing patient complaints

### 4

#### **Description**

Mortality

#### **Timepoint**

Daily

#### **Method of measurement**

Record in checklist

### 5

#### **Description**

Drug side effect (Wheezing, itching, skin rash, edema, and hypotension)

#### **Timepoint**

Daily

#### **Method of measurement**

Question from the patient

### 6

#### **Description**

Reduction in tachypnea

#### **Timepoint**

Daily

#### **Method of measurement**

Medical record

### 7

#### **Description**

Oxygen saturation >94%

#### **Timepoint**

Daily

#### **Method of measurement**

Medical record

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: The intervention group will use Iranian standard treatment protocol for COVID-19 in addition to Ivermectin 3 mg oral tablet at a dose of 0.4 mg/kg manufactured by Alborz Daru of Iran for 3 days as follows: weight 15-24, 6 mg; Weight 35-25, 12 mg; Weight 50-36, 18 mg; Weight 80-5, 24 mg and weight over 80, 0.4 mg/kg

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: In the control group, placebo tablets made by Alborz Daru of Iran with the same shape, color and weight based dose of ivermectin will be used for three days.

#### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Imam and Buali hospitals of Sari, Razi hospital of Qaemshahr, Imam Hossein hospital of Neka and Ima

##### **Full name of responsible person**

Dr Mohammad Sadegh Rezai

##### **Street address**

Bouali Hospital, Pasdaran boulevard, Sari

##### **City**

Sari

##### **Province**

Mazandaran

##### **Postal code**

4815838477

##### **Phone**

+98 11 3334 2334

##### **Email**

drmsrezai@yahoo.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Mazandaran University of Medical Sciences

##### **Full name of responsible person**

Dr. Majid Saeidi

##### **Street address**

Vice chancellor for Research, Moallem square, Sari

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##### **Email**

msaeidi@mazums.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

Mazandaran University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

Academic

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Dr Mohammad Sadegh Rezai

**Position**

Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pediatrics

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Boali Hospital, Pasdaran Blv., Sari

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## Person responsible for scientific inquiries

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Fatemeh Hosseinzadeh

**Position**

Research Expert

**Latest degree**

Master

**Other areas of specialty/work**

Midwifery

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fatima.hzade@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Part of the data is accessible

**When the data will become available and for how long**

Starting in January 2022

**To whom data/document is available**

Physicians

**Under which criteria data/document could be used**

Systematic review articles

**From where data/document is obtainable**

Contact Dr. Mohammad Sadegh Rezai. E-mail:

drmsrezai@yahoo.com

**What processes are involved for a request to access**

**data/document**

After contact, information is sent within a few days  
**Comments**